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NOTICE OF ALLOWANCE AND FEE(S) DUE

7278 7590 DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770 09/08/2010

09/08/2010

EXAMINER

KIM, JENNIFER M

ART LINIT PAPER NUMBER

1628

DATE MAILED: 09/08/2010

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|-------------|----------------------|---------------------|------------------|--|
| 10/624,942 | 07/21/2003 | Marco Pappagallo | 05986/100K504-US1 | 7691 | |
| TITLE OF INVENTION: TREATMENT OF SPINAL MECHANICAL PAIN | | | | | |

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1510 | \$300 | \$0 | \$1810 | 12/08/2010 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT, PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 1SI. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FIEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE DEE and DURI ICATION DEE (if required). Blocks 1 through 5 should be completed where

| appropriate. All further indicated unless correct maintenance fee notifica | correspondence including the delow or directed off | of transmitting the 1336 ig the Patent, advance of herwise in Block 1, by (a | rders and notification of r a) specifying a new corres | naintenance fees will pondence address; a | be mailed to the current nd/or (b) indicating a sep | correspondence address as arate "FEE ADDRESS" for | |
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| mannenance ree nonmeations. CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address) | | | | Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. | | | |
| DARBY & DAP P.O. BOX 770 Church Street St | tation | 72010 | I bo | Certify | icate of Mailing or Trans | smission g deposited with the United st class mail in an envelope above, or being facsimile late indicated below. | |
| New York, NY | 10008-0770 | | | | | (Depositor's name) | |
| | | | _ | | | (Signature) | |
| | | | | | | (Date) | |
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| EXAM | | ART UNIT | CLASS-SUBCLASS | | | | |
| | NIFER M ence address or indicatio | I628 | 514-089000 2. For printing on the p | | | | |
| CFR 1.53). Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. These Address' indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON | | | registered attorney or agent) and the names of up to 2 registered patent attorneys or agent). If no name is 3 listed, no name will be printed. | | | | |
| (A) NAME OF ASSI | GNEE | | (B) RESIDENCE: (CITY | and STATE OR CO | UNTRY) | locument has been filed for | |
| Please check the appropr | riate assignee category or | categories (will not be pr | · | | | oup entity Government | |
| 4a. The following fee(s) Issue Fee Publication Fee (N | No small entity discount p | | Payment of Fee(s): (Plea A check is enclosed. Payment by credit car The Director is hereby overpayment, to Depo | d. Form PTO-2038 is | s attached. | shown above) eficiency, or credit any an extra copy of this form). | |
| | ns SMALL ENTITY state | is. See 37 CFR I.27. | 11 | | ENTITY status. Sec 37 C | | |
| interest as shown by the | id Publication Fee (if req records of the United Sta | uired) will not be accepte tes Patent and Trademark | a from anyone other than t Office. | ne applicant; a registe | erea autorney or agent; or t | he assignee or other party in | |
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| DARBY & DARBY P.C. | | KIM, JENNIFER M | | |
| P.O. BOX 770 | | | ART UNIT | PAPER NUMBER |
| Church Street Station New York, NY 10008-0770 | | | 1628 DATE MAILED: 09/08/2010 | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 710 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 710 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Application No. Applicant(s) 10/624 942 PAPPAGALLO, MARCO Notice of Allowability Examiner Art Unit JENNIFER M KIM 1628 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308. This communication is responsive to 8/13/2010. The allowed claim(s) is/are 2-4, 7, 9 and 11. 3. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) \square All b) ☐ Some* c) ☐ None of the: 1. T Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)). * Certified copies not received: _____. Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. THIS THREE-MONTH PERIOD IS NOT EXTENDABLE. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. CORRECTED DRAWINGS (as "replacement sheets") must be submitted. (a) Including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached 1) hereto or 2) to Paper No./Mail Date (b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d). 6. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

| Att | achment(s) | |
|-----|------------|--|
| | Notice of | |

- Notice of References Cited (PTO-892)
- Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO/SB/08),
- Examiner's Comment Regarding Requirement for Deposi
 of Biological Material
- 5. \square Notice of Informal Patent Application
- Interview Summary (PTO-413), Paper No./Mail Date .

9. ☐ Other .

- 7. Examiner's Amendment/Comment
- 8. X Examiner's Statement of Reasons for Allowance

/JENNIFER M KIM/

Primary Examiner, Art Unit 1628

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicants' amendments and remarks submitted August 13, 2010 have been entered and considered. The amendments and remarks are persuasive to place the application in condition for allowance.

The instant claims are drawn to a specific patient population suffering from chronic mechanical back pain which is not disclosed or suggested by Fox of record.

Fox of record in his results (page 6 [0103]) that pamidronate was ineffective in reversing inflammatory mechanical hyperalgesia. Therefore, there is no expectation of success of treating chronic mechanical back pain specifically defined by instant specification page 7, with administration of pamidronate that is taught to be ineffective in reversing mechanical hyperalgesia in rats.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1628

Jmk

September 2, 2010